DETAILED ACTION

Response to Arguments

1. Applicants' arguments, filed 3/31/2010, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

2. Applicant's arguments with respect to claim1-4, 14-18 and 28 have been considered but are moot in view of the new ground(s) of rejection.

The new ground of rejection, presented below, is necessitated by the claim amendment to claims 1 and 15.

Claim Rejections - 35 USC § 103

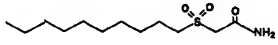
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-4, 14-18 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Townsend et al. (WO 99/10321 A2; 1999; cited in a prior Office Action).

This rejection is necessitated by the claim amendment proviso amending independent claims 1 and 15.

Townsend teaches a method for treating a mycobacterial infection by administering to an animal a pharmaceutical composition containing a compound with the formula R-SO_n-Z-CO-Y, which may be used to inhibit growth of mycobacterium,

including *Mycobacterium tuberculosis* (abstract); treatment of human patients (p. 8, line 10) and animals (claim 8), including cattle and sheep (p. 8, lines 7-8); R is a hydrocarbon, such an an alkyl (p. 5, line 23), n can be 1 (p. 5, line 24), Z is a hydrocarbon linking moiety (p. 5, line 25), and Y is a hydrocarbon linking moiety that may contain a heteroatom (p. 5, line 25); compounds taught include SI-73 (p. 20, Table 1), depicted here:

Compound #		MTB	BCG	MAI
SI-73		3.12		12.50

Amounts taught include amounts to achieve serum concentrations from about 1 ng to about 10 µg/mL, typically 0.1 to 10 µg/mL (p. 9, lines 5-6).

Townsend does not specifically teach the compound of Formula VIII of instant claims 1 and 15, a secondary amine, but only teaches the closely related primary amine, SI-73.

The SI-73 compound is identical to instant claimed compound VIII for the portion of the molecule of R-SO_n-Z-CO (R would be a linear C10 alkyl chain, n would be 1 and Z would be CH_2), but not for Y (Y is the primary amine group NH_2 in SI-73; in contrast, the instant claimed compound VIII would correspond to Y being the methyl amino acetate moiety, $NHCH_2C(O)OCH_3$). The compound SI-73 is a primary amine, whereas the instant claimed compound VIII is a secondary amine. Considering that amino acetate groups ($NHCH_2COOH$) are exemplified in the compounds of Table 1 (see HIII-56, p. 20, Table 1) and methoxy carboxylic acid moieties (COOMe) are also depicted (see HIII-302, p. 20 & JRG-I-31, p. 21), it is clear that the NHCH2C(O)OCH_3 is within the

scope of the Y options taught by Townsend, and is obvious taking the choices for HIII-56 and JRG-I-31 or HIII-302, renders obvious the choice $NHCH_2C(O)OCH_3$ for Y, which would give the instant claimed compound VIII, when the identical choices for $R\text{-}SO_n\text{-}Z\text{-}CO$ are selected, as in compound SI-73. It is noted that $NHCH_2C(O)OCH_3$ for Y is not excluded by the proviso of the last line of claims 1 and 15, as it does not read on the compounds that are excluded.

The secondary amine compound of the instant claims, compound VIII, is obvious over the teaching of SI-73, a primary amine. *Ex parte Bluestone*, 135 USPQ 199 indicates that homology is demonstrated when a reference compound is so closely related to the claimed compound that a chemist would find the difference an obvious variation; the difference found in this case is primarily the one that exists between a secondary and a tertiary amine; that in this case the variation involved is not seen to be of such character as would lead to any significant modification of fungicidal activity (135 USPQ 200, Item [2]). In the instant case the difference between SI-73 and the claimed compound VIII is the difference between a primary amine and a secondary amine; both of these compounds have recognized activity treating mycobacterium infections. Very similar Y groups are clearly depicted, as discussed above. Therefore, based on *Ex parte Bluestone*, instant claimed compound VIII, a secondary amine, is taken to be obvious over the Townsend compound SI-73, a primary amine, with a view of the very similar selections for Y taught by Townsend.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify SI-73, by substituting primary amine moiety NH_2 taught with the the

methyl amino acetate moiety, $NHCH_2C(O)OCH_3$, obvious over the teachings of Townsend, giving instant compound VIII. It would have further been obvious to administer this compound in the treatment of a human or animal, including to cattle or sheep infected with *Mycobacterium tuberculosis*, giving the instantly claimed methods. The motivation would have been the expectation, as indicated in *Ex parte Bluestone*, that the secondary amine compound of the instant claims, with a similar secondary amine moiety to those taught by Townsend, would had similar anti-mycobacterium activity as that taught for SI-73, including activity against the infections taught. It would also have been obvious to optimize the amount for optimal efficacy against *M. tuberculosis*, as described by Townsend (at 2nd paragraph of p. 9), for optimizing the treatment method of a human or animal subject infected with *M. tuberculosis*, without harming the subject being treated; administration of an optimized amount (or specific amounts taught) are taken to satisfy the "effective amount" requirement of claims 1 and 15. The motivation would have been the routine optimization of conditions for treating *M. tuberculosis* infection.

With respect to the language of claim 1, "being able to decrease ATP levels…and not kill mammalian cells during the same time period", and the language "overexpression of the b-subunit of ATP synthase", required by claim 15, administration of the optimized effective amount of this compound (or at the same doses as disclosed by applicant (see instant specification, p. 11, last two lines)) would have been expected to have been characterized by each of these claimed limitations, absent evidence to the contrary.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe inherently includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Applicant argues with respect to the previous rejection, also based on Townsend, that the amended claim language proviso, of the last three lines of claims 1 and 15 excludes compounds of formula R-SO_n-Z-CO-Y, which expressly excludes the compounds disclosed in Townsend.

The rejection is not based on anticipation of the instant method claims over a method involving the Townsend compounds, but over an obvious method where the prior art compounds of Townsend would have been modified to arrive at instantly claimed compound VIII, and the administration of this compound to treat microbially-based infection, rendering the instant method claims obvious. The compound of formula VIII, obvious based on modification of the Townsend compounds, and on *Ex parte Bluestone*, is not excluded by the proviso language of claims 1 and 15, but is specifically claimed.

Claim Objections

4. Claims 1-4, 14-18 and 28 are objected to because of the following informalities: the amended proviso language of the last three lines of independent claims 1 and 15

does not exclude any subject matter from the claims; none of the positively recited eight compounds of the claims group are excluded by the prioviso language now recited; therefore the amended proviso language adds no limitation to the subject matter and is extraneous. Appropriate correction is required.

Conclusion

5. No claim is allowed.

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIMOTHY P. THOMAS whose telephone number is (571) 272-8994. The examiner can normally be reached on Monday-Thursday 6:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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